

Translation

PATENT COOPERATION TREATY

PCT/EP2003/011540



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 2140/Dr.Got/WeS | FOR FURTHER ACTION See Form PCT/IPEA/416 | |
| International application No. PCT/EP2003/011540 | International filing date (day/month/year) 18 October 2003 (18.10.2003) | Priority date (day/month/year) 20 December 2002 (20.12.2002) |
| International Patent Classification (IPC) or national classification and IPC A61K 9/28 | | |
| Applicant RÖHM GMBH & CO.KG | | |

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| 1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. |
| 2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet. |
| 3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). |
| 4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application |

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|--|---|
| Date of submission of the demand 27 April 2004 (27.04.2004) | Date of completion of this report 10 January 2005 (10.01.2005) |
| Name and mailing address of the IPEA/EP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ The international application as originally filed/furnished
- ☒ the description:
- pages _____ 1-31 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- pages _____ 1-22 _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|----------|-----|
| Novelty (N) | Claims | 1-20, 22 | YES |
| | Claims | 21 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-22 | NO |
| Industrial applicability (IA) | Claims | 1-22 | YES |
| | Claims | | NO |

2. Citations and explanations

Reference is made to the following documents:

- D1: WO 00/05307 A (ROTH ERNA; MEIER CHRISTIAN (DE); ROEHM GMBH (DE); PETEREIT HANS UL) 3 February 2000 (2000-02-03)
- D2: ABLETSCHAUER C. B. ET AL: "FILM COATING OF PELLETS WITH INSOLUBLE POLYMERS OBTAINED IN SITU CROSSLINKING IN FLUIDIZED BED" JOURNAL OF CONTROLLED RELEASE, ELSEVIER SCIENCE PUBLISHERS B.V. AMSTERDAM, NL, No. 27, 1993, pages 149-156, XP009025431 ISSN: 0168-3659
- D3: GB-A-1 576 075 (UNION CARBIDE AUSTRALIA) 1 October 1980 (1980-10-01)
- D4: EP-A-1 240 826 (WISSLER ERHARD) 18 September 2002 (2002-09-18)
- D5: US-B1-6 378 789 (SEAMAN JR CHARLES E ET AL) 30 April 2002 (2002-04-30)
- D6: EP-A-0 519 870 (SPIRIG AG) 23 December 1992 (1992-12-23)

Novelty:

The present application does not meet the requirements of PCT Article 33(1) because the

subject matter of claim 21 lacks novelty (PCT Article 33(2)). The subject matter of claim 21 concerns drum coaters, coating pans, fluidised bed apparatus or spray separators, containing one or more triple-feed nozzles. The existence of a spraying device with a triple-feed nozzle is disclosed in the third paragraph on page 20 of the present application.

The subject matter of claims 1, 20 and 22 is novel, since the specific method steps as per claim 1 are not described in the cited prior art.

Inventive step:

According to the current pages 3 and 4, the problem of interest is that of developing a method for producing drugs with the aim of suppressing any incompatibility between the components of the coating mixes.

The problem was solved by the method steps claimed in the present claim 1, in particular by the variation in the quantity of the individual portions during the spraying process.

The teachings of documents D1 and D2 concern methods for producing a coating agent for drugs. The coating techniques or coating agents used in the present application can be taken by a person skilled in the art from the teachings of D1 and D2.

The only difference in the present invention is the variation in the quantity of the individual portions during the spraying process.

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A person skilled in the art would, however, vary the quantities during a spraying process according to the desired coating and drug, without thereby being inventive. In the light of the information relating to spraying devices with triple-feed nozzles (disclosed in the third paragraph on page 20 of the present application), a person skilled in the art would be familiar with the advantages of and the results achieved with spraying devices with triple-feed nozzles and would clearly derive the solution proposed in the present application.

Furthermore, the present application does not show any unexpected effects or properties based on concentration gradients. The current examples are also not directed to the presence of a concentration gradient.

Consequently, the subject matter of claim 1 does not involve an inventive step.

The same reasoning applies to independent claims 20 and 22.